

FALL TECHNICAL CONFERENCE 2008

Marriott Bethesda North Hotel and Conference Center, North Bethesda, MD
October 28 - October 30, 2008

SPEAKING FACULTY INCLUDES:

- Wallace Adams, Ph.D., Science Team, Office of Generic Drugs, FDA
- Deborah Autor, Esq., Director, Office of Compliance, CDER, FDA
- Gary Buehler, R.Ph., Director, Office of Generic Drugs, CDER, FDA
- Dale Conner, Pharm.D., Director, Division of Bioequivalence I, Office of Generic Drugs, FDA
- Barbara Davit, Ph.D., J.D., Director of the Division of Bioequivalence II, Office of Generic Drugs, CDER, FDA
- Norman Drezin, Esq., President, Drezin Consultants, LLC
- Gary Gensinger, M.B.A., Director, Regulatory Review Support Staff, CDER, FDA
- Lillie Golson, R.Ph., MSA, Team Leader, Labeling Branch, Office of Generic Drugs, FDA
- Martin Shimer, R.Ph., Regulatory Management Officer, Regulatory Support Branch, Office of Generic Drugs, FDA
- Neal Sweeney, Ph.D., Team Leader, Microbiology Review Team, Office of Generic Drugs, FDA
- C.T. Viswanathan, Ph.D., Associate Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA
- Helen Winkle, Director, Office of Pharmaceutical Science, CDER, FDA
- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA
- Lawrence Yu, Ph.D., Director for Science, Office of Generic Drugs, FDA

WORKSHOPS FOR INDUSTRY PROFESSIONALS

Pre-conference Project Manager Workshop
Face-to-face interaction with 25 Office of Generic Drugs project managers.
Space is limited. Separate registration is required.

NEW: Pre-Conference SPL Workshop
Full-day session with FDA on structured product labeling.
Space is limited. Separate registration is required.

October 28, 2008 • Pre-Conference Project Manager Workshop*
Pre-Conference SPL Workshop*

*Note: separate registration is required for workshop

October 29-30, 2008 • Fall Technical Conference

Our speaking faculty is comprised of more than dozen top FDA officials



Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Helen Winkle
Director, Office of Pharmaceutical Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Gary Buehler, R. Ph.
Director, Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Deborah Autor, Esq.
Director, Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration



Dale Conner, Pharm. D.
Director, Division of Bioequivalence I
Office of Generic Drugs
U.S. Food and Drug Administration

**Earn
ACPE
Credits!**

CONTINUING EDUCATION CREDITS

FOR PHARMACISTS

Fall Technical Conference Goals and Objectives - October 29-30, 2008

The purpose of this two-day seminar is to assist regulatory and technical personnel to maintain current knowledge of the scientific and regulation requirements for submission and approval of ANDAs. These topics provide an up-to-date description of the key scientific and regulatory challenges that face the generic pharmaceutical industry. Upon completion of this conference, the attendee should be able to: 1) understand the regulatory requirements for filing an ANDA and the content and format of an e-CTD ANDA; 2) understand the technical components of a quality overall summary of the chemistry, manufacturing and controls section of an ANDA; 3) identify critical CGMP requirements necessary for the manufacture of generic pharmaceuticals; 4) understand key issues of bioequivalence testing; and 5) identify common deficiencies in Drug Master Files.

Project Manager Workshop Goals and Objectives- October 28, 2008

This four hour workshop will focus on improving the understanding of the process for approval of abbreviated new drug application and is intended for industry regulatory affairs personnel with three years or less of experience. Upon completion of this workshop, participants should be able to:

1. Describe the critical steps of the ANDA review process;
2. Understand key regulatory requirements for submission of ANDAs; and
3. Identify key factors for effective communication with FDA staff

GPhA, and FDA, in cooperation with the University of Wisconsin, are co-sponsoring this conference and workshop.



GPhA Project Manager Workshop, October 28

"Extension Services for Pharmacy at the University of Wisconsin-Madison School of Pharmacy is accredited by the Accreditation Council on Pharmacy Education as a provider of continuing pharmaceutical education. This workshop is approved for 4 hours or 0.4 continuing education units (CEUs). Pharmacists will be required to complete a program evaluation and statements of credit for continuing pharmaceutical education participation will be mailed within one month of the meeting. ACPE # 073-999-08-095-L04"



GPhA/FDA Workshop on SPL Release Four - Drug Listing/Establishment Registration, October 28

"Extension Services for Pharmacy at the University of Wisconsin-Madison School of Pharmacy is accredited by the Accreditation Council on Pharmacy Education as a provider of continuing pharmaceutical education. This workshop is approved for 6 hours or 0.6 continuing education units (CEUs). Pharmacists will be required to complete a program evaluation and statements of credit for continuing pharmaceutical education participation will be mailed within one month of the meeting. ACPE # 073-999-08-097-L04"



GPhA Fall Technical Conference, October 29-30

"Extension Services for Pharmacy at the University of Wisconsin-Madison School of Pharmacy is accredited by the Accreditation Council on Pharmacy Education as a provider of continuing pharmaceutical education. This workshop is approved for 13 hours or 1.3 continuing education units (CEUs). Pharmacists will be required to complete a program evaluation and statements of credit for continuing pharmaceutical education participation will be mailed within one month of the meeting. ACPE # 073-999-08-096-L04"

Meeting Registration

		Project Manager Workshop ONLY	\$595
GPhA Members	\$1,770	Project Manager Workshop / Conference Registration	\$525
Non-Members	\$2,080	SPL Workshop ONLY	\$675
Government	\$420	SPL Workshop w/ Conference Registration	\$625

Register online today at www.gphaonline.org

Cancellation requests must be made in writing and postmarked no later than October 20, 2008. All cancellations are subject to a \$300 processing fee. No refunds will be made for cancellations received after October 20, 2008.

Hotel Information

Make hotel reservations at the Marriott Bethesda North Hotel and Conference Center by October 6, 2008 for GPhA's preferred rate. To receive the preferred rate you must first register for the event. Please refer to the meeting name: "GPhA Fall Technical." Reservations made without prior registration and/or after October 6, 2008 are subject to hotel standard rates and availability.

Marriott Bethesda North Hotel and Conference Center

5701 Marinelli Road, Bethesda, MD 20852 Toll Free: 800-859-8003

Tips for Meeting Attendees

Meeting Attire: For the workshops and plenary sessions, the expected meeting attire is business casual. Evening casual attire is appropriate for the Fall Technical Conference dinner buffet and party on the evening of Wednesday, October 29.



FALL TECHNICAL CONFERENCE 2008

Dear Industry Colleagues,

It's been an exciting and challenging year for technical and regulatory affairs professionals – which means we have a great deal to hear about and discuss at the 2008 Fall Technical Conference. This year's industry/agency collaboration, "GPhA/FDA: Advancing pharmaceutical science for better health," provides the ideal opportunity to stay abreast of the ever-changing regulatory and technical landscape, as well as to have a dialogue with key agency officials who are responsible for America's generic drug program.

We have excellent participation from a host of FDA officials offering insight and advice on FDA's approach to manufacturing science as well as its new initiatives to address bioequivalence, product safety and good manufacturing practices.

Distinguished Speakers

We are honored to open our conference with an address on FDA issues and initiatives from Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER). Our distinguished speaking faculty also includes presentations by Gary Buehler, Director of the Office of Generic Drugs; Helen Winkle, Director of the Office of Pharmaceutical Science, CDER and Deborah Autor, Director of the Office of Compliance, CDER, along with a number of other distinguished science and regulatory experts from FDA.

Featuring Two Pre-Conference Workshops – Register Early!

We are pleased to announce that our ever-popular "Regulatory Affairs - Project Manager Information Exchange" is back. This pre-conference event on October 28 facilitates interaction between our

attendees and Office of Generic Drugs' Project Managers. And on the same day, we host the first-ever, "SPL Release Four - Drug Listing/Establishment Registration Workshop," an important and timely topic that merits a full-day session. Due to limited capacity, we encourage you to register early for these unique, interactive sessions.

Networking and Evening Entertainment

On the evening of October 29, GPhA brings a new twist to an event that has become an industry tradition. Join us for a Carnivale-style party and dinner buffet, complete with a Latin band and many fun-filled activities. This evening event, combined with our breakfasts, luncheons and meeting breaks, provides an ideal setting for relaxed, professional networking with industry colleagues.

Each year the Fall Technical Conference draws a wider audience. In 2007, attendance grew to more than 400 participants for the second year in a row. Please join us again this year as we partner with FDA for this unparalleled industry event. We look forward to seeing you there.

Sincerely,



Kathleen Jaeger
President and CEO, GPhA



GPhA Thanks Our Sponsors to Date:

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Media Sponsor:

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Register online today at www.gphaonline.org

OPTIONAL PRE-CONFERENCE PROJECT MANAGER WORKSHOP • OCTOBER 28, 2008

11:30a.m. - 12:30p.m.	<i>Pre-Conference Workshop Registration</i>
12:30p.m. - 2:30p.m.	Regulatory Affairs - Project Manager Information Exchange Workshop Leaders: Office of Generic Drugs Project Managers Industry Representatives
2:30p.m. - 3:00p.m.	<i>Refreshment Break</i>
3:00p.m. - 5:00p.m.	Regulatory Affairs - Project Manager Information Exchange
5:00p.m.	Pre-Conference Workshop Concludes

OPTIONAL PRE-CONFERENCE SPL WORKSHOP • OCTOBER 28, 2008

8:00a.m. - 9:00a.m.	<i>Breakfast and Workshop Registration</i>
9:00a.m. - 10:30a.m.	GPhA/FDA: SPL Release Four - Drug Listing/Establishment Registration Workshop Workshop Leaders: Office of Generic Drugs Industry Representatives
10:45a.m. - 11:00a.m.	<i>Refreshment Break</i>
11:00a.m. - 12:30p.m.	Workshop continues
12:30p.m. - 1:30p.m.	<i>Lunch</i>
1:30p.m. - 3:00p.m.	Workshop continues
3:00p.m. - 3:15p.m.	<i>Refreshment Break</i>
5:00p.m.	Pre-Conference Workshop Concludes
5:00p.m. - 6:30p.m.	<i>Reception for Workshop Participants</i>
5:00p.m. - 7:00p.m.	<i>2008 Fall Technical Conference Registration</i>

FALL TECHNICAL CONFERENCE • OCTOBER 29, 2008

7:30a.m. - 8:30a.m.	<i>Registration and Breakfast Buffet</i>
8:30a.m. - 8:45a.m.	Welcome and Introduction <i>Kathleen Jaeger</i> President and CEO, GPhA
8:45a.m. - 9:15a.m.	CDER Issues and Initiatives <i>Janet Woodcock, M.D.</i> Director, Center for Drug Evaluation and Research, FDA
9:15a.m. - 10:15a.m.	Panel: Regulatory and Filing Challenges for ANDAs <i>Martin Shimer, R.Ph.</i> Branch Chief, Regulatory Support Branch, Office of Generic Drugs, FDA <i>Industry Representative</i>
10:15a.m. - 10:45a.m.	<i>Refreshment Break</i>
10:45a.m. - 11:15a.m.	Panel: Regulatory and Filing Challenges for ANDAs (continued)
11:15a.m. - 12:30p.m.	OGD Initiatives and Outlook <i>Gary Buehler, R.Ph.</i> Director, Office of Generic Drugs, FDA

FALL TECHNICAL CONFERENCE • OCTOBER 29, 2008

12:30p.m. - 1:45p.m.

Lunch

1:45p.m. - 2:45p.m.

Current Labeling Landscape for ANDAs

Lillie Golson, R.Ph.

Team Leader, Labeling Branch, Office of Generic Drugs, FDA

2:45p.m. - 3:45p.m.

Office of Compliance Update: 2008 and Beyond

Deborah Autor, Esq.

Director, Office of Compliance, Center for Drug Evaluation and Research, FDA

3:45p.m. - 4:15p.m.

Refreshment Break

4:15p.m. - 5:15p.m.

Plenary Session	Breakout Session
Current Trends in Division of Scientific Investigation Inspections <i>C.T. Viswanathan, Ph.D. Associate Director,</i> Division of Scientific Investigations Office of Compliance, FDA	Drug Advertising Issues/Generic Industry <i>Norman Drezin, Esq.</i> President Drezin Consultants, LLC

5:30p.m. - 7:00p.m.

Networking Reception

7:00p.m. - 9:30p.m.

Dinner Buffet and Party

FALL TECHNICAL CONFERENCE • OCTOBER 30, 2008

7:30a.m. - 8:30a.m.

Breakfast Buffet

8:30a.m. - 9:00a.m.

Pharmaceutical Quality Initiatives

Helen Winkle

Director, Office of Pharmaceutical Science, Center for Drug Evaluation and Research, FDA

9:00a.m. - 10:30a.m.

Plenary Session	Breakout Session
Optimizing e-CTDs <i>Gary Gensinger, MBA</i> Director, Regulatory Review Support Staff, CDER, FDA	Sterility Assurance <i>Neal Sweeney, Ph.D.</i> Team Leader, Microbiology Review Team, OGD, FDA <i>Lynne Ensor, Ph.D.</i> Microbiology Team Leader, OGD, FDA

10:30a.m. - 11:00a.m.

Refreshment Break

11:00a.m. - 12:00p.m.

Plenary Session	Breakout Session
Legal Challenges Under MMA and FDA AA <i>Elizabeth Dickinson (invited)</i> Associate Chief Counsel for Drugs FDA	Overview of Clinical Endpoint Issues and Inhaled Drugs <i>Wallace Adams, Ph.D.</i> Science Team, OGD, FDA <i>OGD Staff (TBA)</i>

12:00p.m. - 1:15p.m.

Lunch

1:15p.m. - 3:15p.m.

CMC Panel: FDA's New Perspective on Post-Approval Supplements

Paul Schwartz, Ph.D.

Deputy Division Director, Chemistry Review Division, Office of Generic Drugs, FDA

Update on Question-based Review Issues

Lawrence Yu, Ph.D.

Deputy Director for Science, Office of Generic Drugs, FDA

Industry Representative

3:15p.m. - 3:30p.m.

Refreshment Break

3:30p.m. - 5:00p.m.

Regulatory Perspectives on Bioequivalence

Dale Conner, Pharm. D.

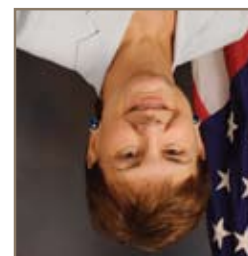
Director, Division of Bioequivalence I, Office of Generic Drugs, FDA

Barbara Davit, Ph.D., J.D.

Director, Division of Bioequivalence II, Office of Generic Drugs, FDA

5:00p.m.

Conference Concludes



Janet Woodcock, M.D.
Director, Center for Drug Evaluation
and Research
U.S. Food and Drug Administration



Helen Winkle
Director, Office of
Pharmaceutical Science
Center for Drug Evaluation
and Research
U.S. Food and Drug Administration



Gary Buehler, R. Ph.
Director, Office of Generic Drugs
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Project Manager Workshop*

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**The Generic Industry's Premier
Science & Regulatory Meeting!**
Advancing Pharmaceutical Science for Better Health



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